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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,037	06/30/2005	Akinori Hanano	19036/40139	9381
4743 7590 07/02/2007 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			EXAMINER VAKILI, ZOHREH	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 07/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,037	Applicant(s) HANANO, AKINORI	
	Examiner Zohreh Vakili	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1 and 5-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/30/2004</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1, 5-11 are presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Norton et al. (US Patent No. 5976556)

Norton et al. teach Novel compositions comprising one or more of an acid protease and an acidic buffer, the acidic buffer comprising an acid and a pharmaceutically or cosmetically acceptable carrier, vehicle or excipient, useful for treating or preventing abnormal biological conditions, diseases or disorders, and/or for improving the texture or appearance of the skin, and/or for enhancing epidermal exfoliation and/or for enhancing epidermal cell renewal and to methods for the use of the compositions. The acidic buffer comprises inorganic and/or organic acids or mixtures thereof with a pharmaceutically or cosmetically acceptable carrier, vehicle or excipient. The buffer is capable of reducing the pH of the surface of the skin to less than pH 5.5 and is susceptible to neutralization by normal epidermal processes. Such types of abnormal biological conditions, diseases or disorders include skin atrophy,

Art Unit: 1614

i.e., the thinning and/or general degradation of the dermis often characterized by a decrease in collagen and/or elastin as well as decreased number, size and doubling potential of fibroblast cells, and other maladies including, but are not limited to dry skin, severe dry skin, dandruff, acne, keratoses, psoriasis, eczema, skin flakiness, pruritus, age spots, lentigines, melasmas, wrinkles, warts, blemished skin, hyperpigmented skin, hyperkeratotic skin, inflammatory dermatoses, age-related skin changes and skin in need of cleansers (see abstract). This invention relates to novel compositions comprising one or more of an acid protease enzyme and an acidic buffer, the acidic buffer comprising an acid and a pharmaceutically or cosmetically acceptable carrier, useful for treating or preventing abnormal skin conditions, diseases or disorders, and/or for improving the texture or appearance of the skin, and/or for enhancing epidermal exfoliation, and/or for enhancing epidermal cell renewal and to methods for the use of the compositions (see col. 1, lines 6-15). The acidic buffer is a composition which when topically applied to the skin, temporarily lowers the pH of the surface of the skin to less than about pH 5.5 but not lower than about pH 1.0, preferably to between about pH 2.5 and about pH 4.5. The acidic buffer composition comprises at least one acid and a pharmaceutically or cosmetically acceptable carrier, vehicle or excipient. The acid component of the buffer can be an inorganic or an organic acid or mixtures thereof (see col. 4, lines 39-45). EXFOLIATION is defined as the detachment and shedding of superficial cells of an epithelium or from any tissue surface (see col. 7, lines 39-40). The acidic buffer is a composition which when topically applied to the skin, temporarily lowers the pH of the surface of the skin to less than about pH 5.5, but not lower than

Art Unit: 1614

about pH 1.0, preferably about pH 2.5 to about pH 4.5. The acidic buffer composition comprises at least one acid and a pharmaceutically or cosmetically acceptable carrier, vehicle, or excipient (see col. 10, lines 8-11). The acid component of the acidic buffer of the composition can be an organic acid or an inorganic acid or mixtures thereof (see col. 10, lines 24-26). Examples of such acids include any molecule that can be manipulated in any composition to buffer the epidermal pH at pH ranges from about 0.1 to about 7 including, but are not limited to, lactic acid, sorbic acid, phosphoric acid, citric acid, **glycolic acid**, malic acid, gluconic acid, pyrophosphoric acid, triphosphoric acid, polyphosphoric acid, sodium bisulfate and potassium bisulfate. It should be understood that two or more acids can be used in combination such that the combined amount in weight percent is within the ranges mentioned above (see col. 10, lines 38-47). The acidic buffer also contains a component which is a pharmaceutically or cosmetically acceptable carrier, vehicle, or excipient. Examples of such pharmaceutically acceptable carriers, vehicles, or excipients are well known to those skilled in the art (see col. 10 48-52). The compositions of the present invention intended for topical application may contain carrier, excipient, or vehicle ingredients such as, for example, water, acetone, ethanol, ethylene glycol, propylene glycol, butane-1,3-diol, isopropyl myristate, isopropyl palmitate, mineral oil, and mixtures thereof to form lotions, tinctures, creams, emulsions, gels, or ointments which are non-toxic and pharmaceutically, cosmetically, or dermatologically acceptable. Additionally, moisturizers or humectants can be added to the present compositions if desired (col.

Art Unit: 1614

10, lines 61-67 & col.11, lines 1-3). Methods of Use of the Compositions of the Present Invention: The present invention provides methods for enhancing epidermal exfoliation and/or for enhancing epidermal cell renewal. Such methods comprise topically administering to an area of a subject's skin an effective amount of a composition of the present invention, which comprises an acid protease enzyme exhibiting proteolytic activity below about pH 5.5 and insignificant activity at or above about pH 5.5 and an acidic buffer which lowers the pH of the surface of the skin to below about pH 5.5 for a period of time effective to enhance epidermal exfoliation and/or enhance epidermal cell renewal, the acidic buffer being subject to neutralization by natural epidermal processes (see col. 12, lines 8-19). The present invention also provides methods for improving the texture and/or appearance of skin. Such methods comprise administering to an area of a subject's skin an effective amount of a composition of the present invention, which comprises an acid protease enzyme exhibiting proteolytic activity below about pH 5.5 and insignificant activity at or above about pH 5.5 and an acidic buffer which lowers the pH of the surface of the skin to below about pH 5.5 for a period of time effective to improve the texture and/or appearance of skin, the acidic buffer being subject to neutralization by natural epidermal processes (see col. 12, lines 20-31). A preferred method of administering an effective amount of a composition of the present invention for any of the methods described above on an area of skin is via topical application. The amount of the acidic buffer and acid protease in the final composition and frequency of topical application to the skin can vary widely, depending upon factors such as the particular skin disorder,

Art Unit: 1614

the severity of the skin disorder, the location and/or type of the skin involved, the subject's skin sensitivity, and the degree of treatment desired. It is well within the purview of the skilled artisan to regulate dosages according to the subject's need (see col. 12, lines 62-67 & col. 13, lines 1-5). The composition according to claim 2 wherein the pharmaceutically or cosmetically acceptable carrier, vehicle or excipient component of the acidic buffer is selected from the group consisting of lotions, tinctures, creams, emulsions, gels, ointments, water, water-workable cream, **polyvinyl alcohol**, hydroxyethyl cellulose, cellulose, hydrophilic acrylic polymer, emollients, skin moisturizing components, enzyme stabilizers, glycerol, surfactants, preservatives, hydrophilic thickening agents used in pharmaceutical formulations and mixtures thereof (see col. 21, claim 3).

Norton et al. teach of a composition for enhancing epidermal exfoliation that comprises of organic and inorganic acid, glycolic acid, and polyvinyl alcohol with pH of composition ranging from 0.1 to about 7. The preferred method of administration is applying the composition on an area of skin via topical application. Consequently, the reference anticipates the claimed invention defined in claims 1, 5-11.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

Art Unit: 1614

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili
Patent Examiner
1614

June 18, 2007


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER